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TITLE: Catheter member with bondable layer

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Abstract Text - ABTX (1):
The invention is directed to a catheter formed at least in part of a multilayered member having a first layer which is **fusion** bondable to another catheter component such as the skirt of an inflatable balloon and a second layer which is adjacent the first layer having a **melting point** greater than the first layer so that the multilayered member of the catheter is not deformed when the other catheter component is **fusion** bonded to the first layer of the multilayered member. The second layer is preferably lubricious in nature. In one embodiment of the invention, the multilayered member is a tubular element with the lubricious second layer defining an inner lumen extending within the tubular element. The outer layer of the tubular member may extend beyond the distal end of the inner layer and form a non-traumatic distal tip. Alternatively, a flexible non-traumatic distal tip may be **fusion** bonded to at least the outer layer of the multilayered tubular member.

Brief Summary Text - BSTX (3):
In a typical PTCA procedure a dilatation **balloon catheter** is advanced over a **guidewire** to a desired location within the patient's coronary anatomy where the balloon of the dilatation catheter is properly positioned within the stenosis

to be dilated. The balloon is then inflated with radiopaque liquid at relatively high pressures (generally 4-12 atmospheres) to dilate the stenosed region of the diseased artery. One or more inflations may be needed to effectively dilate the stenosis. The catheter may then be withdrawn from the stenosis or advanced further into the patient's coronary anatomy to dilate additional stenoses.

Brief Summary Text - BSTX (4):

In addition to the dilation of stenoses, **balloon catheters** similar to those described above are used to deploy stents within a patient's body lumen after a dilatation has been completed or simultaneously with the dilatation in order to maintain lumen patency. In this case an expandable stent is disposed about the exterior of the balloon on the distal extremity of the catheter and the catheter is then advanced within the patient's body lumen until the stent mounted on the exterior of the balloon is at the location in which the stent is to be deployed, e.g. usually at the stenotic site of a previous dilatation. The balloon is inflated so as to expand the stent against the wall defining the body lumen and then the balloon is deflated and the catheter withdrawn from the patient's body lumen.

Brief Summary Text - BSTX (5):

Advances in the development of **balloon catheters** for both dilatation and stent deployment have made the selection of materials difficult because of conflicting requirements. For example, higher dilation pressures has made the sealed bonding of the **balloon the catheter** shaft a greater requirement, but the materials from which the high pressure balloons are made, e.g. polyethylene

terephthalate, polyamide (e.g. nylon) and the like, have limited the materials
to which the balloon can be bonded, and thus, the materials from which the
catheter shaft can be made, particularly the distal extremity of the catheter
shaft where the balloon is located.

Brief Summary Text - BSTX (6):

If the distal tip of an intravascular catheter is to have non-traumatic
characteristics to minimize damage when passing through a body lumen,
additional material limitations come into play because typical non-traumatic
tips are formed from short tubular members made of relatively soft polymeric
material which are secured by adhesive or **fusion** bonding to the distal tip of
the tubular distal extremity of the catheter.

Brief Summary Text - BSTX (11):

The multilayer member of the invention has a first layer which is **fusion**
bondable to another catheter component and an adjacent second layer which has
greater lubricity than the first layer. The first layer preferably has a
melting point which is lower than the **melting point** of the adjacent second
layer so that when the first layer is **fusion** bonded to another catheter
component, the adjacent layer of the multilayer member is not deformed or
otherwise misshapen by the heat from a bonding procedure. In a presently
preferred embodiment of the invention, the multilayered member is in a tubular
form with the second layer on the inside of the tubular member defining an
inner lumen extending through the tubular member. The first layer which has a
melting point lower than that of the second layer forms at least in part the
outer layer of the tubular member.

Brief Summary Text - BSTX (12):

In one aspect of the invention, the catheter has an elongated shaft with a proximal end, a distal end, a port in the distal end and a **guidewire** lumen extending through at least the distal portion of the catheter to and in fluid communication with the port in the distal end of the catheter shaft. In accordance with this aspect, the elongated shaft of the catheter has a multilayer tubular member with a first or outer layer which is **fusion** bondable to another catheter component and a second or inner layer which has lubricious properties. A high strength outer layer may be bonded to at least part of the first layer to provide additional strength and pushability. The first layer should have a **melting point** which is at least 20.degree. C., preferably at least 30.degree. C. lower than the **melting point** of an adjacent polymeric layer, so that the adjacent layer is not distorted by the heat from the **fusion** bonding procedure.

Brief Summary Text - BSTX (13):

The material from which the first layer of the multilayered member, which has a lower **melting point** than the adjacent second layer, is selected so as to be compatible with the polymeric material of the catheter component to which it is to be secured. A presently preferred lower **melting point** polymeric material is a polyolefin based copolymer with not more than 35% (by weight) reactive monomer forming the copolymer. A suitable polyolefin material is copolymerized with one or more monomers selected from the group consisting of carboxylic acid or acrylic acid or anhydride thereof and preferably is unsaturated. A presently preferred polyolefinic material is a polyethylene based adhesive

polymer such as ethylene-acrylic acid copolymer which is sold commercially as PRIMACOR by Dow Chemical Co. or as ESCOR by EXXON or as PLEXAR by Quantum Chemical Corp. Other suitable materials include polymers which have been modified by reactive extrusion having a durometer range of about Shore A 80 to about Shore D 80, preferably about Shore A 90 to about Shore D 70.

Brief Summary Text - BSTX (17):

In one presently preferred embodiment of the invention, the catheter is a dilatation catheter for angioplasty or stent delivery having a balloon on a distal shaft section with a multilayered inner tubular member which extends through and distal to the balloon and which defines at least in part a **guidewire** lumen extending to and in fluid communication with a port in the distal end of the catheter. In this instance, the multilayered inner tubular member has a bondable outer layer and the polymeric material thereof is selected to facilitate the **fusion** bonding of the distal skirt of the balloon to the outer layer of the inner tubular member. The multilayered inner tubular member also has an inner layer having lubricious properties which defines at least part of the **guidewire** lumen.

Brief Summary Text - BSTX (18):

Another embodiment of the invention is directed to an intraluminal catheter wherein the multilayered tubular member forms at least part of the shaft of the intraluminal catheter and the low **melting point** material of the outer bonding layer of the multilayered tubular member extends beyond an adjacent layer to form a non-traumatic distal tip on the catheter shaft.

Brief Summary Text - BSTX (19):

In yet another aspect of the invention, the catheter is provided with a non-traumatic distal tip which is **fusion** bonded to at least the bondable layer on the multilayered tubular member. While a **fusion** bond somewhat limits the selection of material for the bondable layer, the preferred material discussed above, namely the polyethylene based adhesive such as PRIMACOR, ENCOR or PLEXAR facilitates **fusion** bonding to a wide variety of materials including polyethylene, PET, polyamide, polyurethane, PVC and copolymers such as PEBAX.RTM. and HYTREL.RTM. and the like.

Brief Summary Text - BSTX (20):

In most instances the wall thickness of the **fusion** bondable layer of the multilayered tubular member should be less than half the wall thickness of the tubular member, preferably less than 40% of the total thickness of the member. The inner and outer dimensions of the tubular member generally follow the dimensions of other tubular members from which intravascular catheters are made.

Detailed Description Text - DETX (2):

Reference is made to FIGS. 1-2 which illustrate a balloon dilatation catheter 10 embodying features of the invention. Catheter 10 has an elongated shaft 11 with proximal and distal shaft sections 12 and 13, an adapter 14 on the proximal end of the shaft and a dilatation balloon 15 on the distal shaft section spaced proximal to the distal end 16. An inflation lumen 17 extends between the proximal end of shaft 11 and a location spaced proximal to the distal end 16 and is in fluid communication with the interior of the dilatation balloon 15. The catheter shaft 11 is provided with a

multilayered first inner
tubular member 18 and an outer tubular member or jacket 19 of suitable
polymeric material or materials. A **guidewire** receiving lumen 20 extends
through the proximal and distal shaft sections 12 and 13 to the port 21 in the
distal end of the shaft 11. In the distal shaft section 13, the **guidewire**
receiving lumen 20 is defined at least in part by the inner layer 22 of the
first inner tubular member 18.

Detailed Description Text - DETX (3):
The balloon 15 has a distal skirt 23 which is secured by **fusion** bonding to
lower **melting point** polymeric material of the outer layer 24 of the
multilayered first inner tubular member 18 and a proximal skirt 25 which is
secured by suitable means to the distal end of the outer tubular member 19.

Detailed Description Text - DETX (4):
The multilayered tubular members of the invention may have more than two
layers in other configurations. For example, as shown in FIG. 4, a high
strength outer layer 29 may be provided on the exterior of low **melting point**
bonding layer 24. While not shown in the drawings the high strength outer
layer 29 may be removed from the distal portion of the inner tubular member 18
to expose the low **melting point** bonding layer 24. In this manner the outer
layer 29 can provide strength and would still be available for bonding to the
distal skirt 23 of the balloon 15. As shown in FIGS. 1-4 a **guidewire** 30 is
slidably disposed within the inner lumen 20 of the inner tubular member 18.

Detailed Description Text - DETX (6):
A further modification of the present invention is

illustrated in FIG. 5 which depicts the distal extremity of an intravascular catheter 40 formed of a multilayered tubular member 41 wherein the outer layer 42 extends beyond the distal end of the inner layer 43 and is heat shaped so as to form a non-traumatic distal tip 44. A presently preferred method of forming the non-traumatic distal tip 44 is to heat shape the distal portion of the outer layer 42 which extends distally beyond the distal end of the inner layer 43 against the exterior of a mandrel (not shown) disposed within the **guidewire** lumen 45 and an exterior shaping member which heat forms the exterior of the distal tip 44.

Detailed Description Text - DETX (7):

FIG. 6 shows a distal extremity of an intravascular catheter 50 formed in part from a multilayered tubular member 51 having an outer layer 52 formed of bondable polymeric material as previously described, an inner layer 53 and a flexible distal tip 54 which is **fusion** bonded at least to the distal end or the exterior of the outer layer.

Detailed Description Text - DETX (8):

An alternative embodiment of an intravascular catheter 60, as shown in FIG. 7, has a multilayered tubular member 61 with an outer layer 62 formed of the lower **melting point** polymeric material as previously described, an inner lubricious layer 63 and a flexible distal tip 64 bonded to the end or exterior or both of the outer layer 62. The embodiment of FIG. 7 differs from that shown in FIG. 6 by having a multilayered distal tip 64 with an outer layer 65 and an inner layer 66. Preferably, the inner layer 66 is formed of a low **melting point** polymeric material the same as or compatible

with the outer layer
62 to facilitate **fusion** bonding of the distal tip 64 to the exterior of the
tubular member 61.

Detailed Description Text - DETX (9):
The thickness of the bonding layer generally will depend upon the material
from which the layer is formed and the stresses to which the bonding layer will
be exposed to in use. The dimensions of the various catheter components of the
invention may generally follow the dimensions of similar components utilized in
commercially available catheters. For example, for angioplasty catheters and
stent delivery catheters the **guidewire** lumen should accommodate the **guidewire**
having diameters of about 0.010 to 0.035 inch (0.25-0.89 mm), typically about
0.012 to about 0.018 inch (0.30-0.46 mm) so the **guidewire** receiving lumen
should range from about 0.014 to about 0.040 inch (0.36-1.0 mm), preferably
about 0.016 to about 0.023 inch (0.38-0.58 mm). If the catheter is to have
perfusion capabilities, the number, size and distribution of perfusion holes in
the catheter wall (not shown) is controlled to provide a perfusion flow rate of
about 20-60 cc/min, preferably about 30-45 cc/min. The inflated balloon
diameters may range from about 1 to about 5, typically about 2 to about 4 mm.
Balloon lengths may range from about 10-50 mm, typically about 20-40 mm. The
distal shaft section proximal to the balloon may range from about 0.03 to about
0.06 inch (0.76-1.52 mm), typically about 0.035 to about 0.05 inch (0.89-1.27
mm). Balloon burst pressures should be about 10 to about 20 atmospheres
(147-294 psi), preferably about 12 to about 15 atmospheres (176-221 psi). To
the extent not described herein dimensions and materials described in the
references incorporated herein and dimensions and materials

used in
commercially available dilatation and stent delivery catheters may be employed
with the catheters of the present inventions.

Detailed Description Text - DETX (10):
The catheter of the invention may be of a **rapid exchange** type catheter such
as described in U.S. Pat. No. 5,040,548 (Yock), U.S. Pat. No. 4,748,982
(Horzewski et al.), U.S. Pat. No. 5,496,275 (Sirhan et al) and U.S.
application Ser. No. 08/484,267, filed on Jun. 7, 1995, which have been
incorporated herein. In these catheters the **guidewire** lumen extends from a
distal port in the distal end of the catheter shaft to a proximal port spaced
proximally about 7 to about 45 cm, preferably about 15 to about 35 cm, from the
distal end of the catheter shaft.

Claims Text - CLTX (2):
a) an elongated shaft having proximal and distal ends, a port in the distal
end and a **guidewire** lumen extending therein to and in fluid communication with
the port in the distal end;

Claims Text - CLTX (3):
b) the **guidewire** lumen being defined at least in part by a multilayered
tubular member having an inner layer formed of a lubricious polymeric material
and an outer layer formed of a polyolefin polymerized with up to about 35% by
weight of a polymer having reactive monomer groups, the outer layer having a
melting point lower than that of the inner layer; and

Claims Text - CLTX (4):
c) a catheter part **fusion** bonded to the outer layer of the multilayered
tubular layer.

Claims Text - CLTX (9):
6. The catheter of claim 5 wherein the polyolefin adhesive polymer is formed of a copolymer of a polyolefin and up to 30% by weight of a polymer with reactive monomer groups which facilitate **fusion** bonding to the catheter part.

Claims Text - CLTX (18):
15. The catheter of claim 1 having a strengthening layer bonded to an outer surface of the outer layer along a length thereof proximal to a section of the outer layer **fusion** bonded to the catheter part.

Claims Text - CLTX (21):
b) a first catheter part having a first polymer layer with a desired **melting point** formed of a polyolefin copolymerized with up to about 35% by weight of a polymer having reactive monomer groups, and a second polymer layer with a **melting point** greater than the **melting point** of the first polymer layer; and

Claims Text - CLTX (22):
c) a second catheter part **fusion** bonded to the first polymer layer of the first catheter part.

Claims Text - CLTX (26):
20. The catheter of claim 19 wherein the polyolefin adhesive polymer is a copolymer formed with up to 30% by weight of reactive monomer groups which facilitate **fusion** bonding to the second catheter part.

Claims Text - CLTX (31):
a) an elongated shaft having proximal and distal ends, a port in the distal end and a **guidewire** lumen extending therein to and in fluid

communication with
the port in the distal end;

Claims Text - CLTX (32):
b) the **guidewire** lumen being defined at least in part by a multilayered
tubular member having an inner layer formed of a lubricious polymeric material
and an outer layer formed of a polyolefin polymerized with up to about 35% by
weight of a polymer having reactive monomer groups, the outer layer having a
melting point less than that of the lubricious polymeric material of the
adjacent inner layer; and

Claims Text - CLTX (33):
c) a catheter part **fusion** bonded to the outer layer of the inner tubular
layer.

Claims Text - CLTX (38):
29. The catheter of claim 28 wherein the polyolefin is a copolymer formed
with up to 30% by weight of reactive monomer groups which facilitate **fusion**
bonding of the outer layer to the catheter part.

Claims Text - CLTX (43):
a) an elongated shaft having proximal and distal ends, a port in the distal
end and a **guidewire** lumen extending therein to and in fluid communication with
the port in the distal end;

Claims Text - CLTX (44):
b) a multilayered tubular member having an inner layer formed of a
lubricious polymeric material which defines in part the **guidewire** lumen and an
outer layer formed of a polymeric material having a lower **melting point than**
the melting point of the polymeric material of the inner

layer; and

Claims Text - CLTX (54):
39. The catheter of claim 35 wherein the inner layer is formed of polymeric material having a desired **melting point** and the outer layer is formed of a polymeric material having a **melting point** of at least about 20.degree. C. less than the **melting point** of the inner layer.

Claims Text - CLTX (55):
40. The catheter of claim 35 wherein the inner layer is formed of polymeric material having a desired **melting point** and the outer layer is formed of a polymeric material having a **melting point** of at least about 30.degree. C. less than the **melting point** of the inner layer.

Claims Text - CLTX (57):
42. The catheter of claim 35 wherein the polyolefin adhesive polymer is a copolymer which has been formed with up to 30% by weight of a monomer with reactive groups which facilitate **fusion** forming of the distal end of the catheter.

Claims Text - CLTX (62):
b) an inner layer of the tubular member which defines at least in part the lumen extending therein and which is formed of lubricious polymeric material having a desired **melting point**; and

Claims Text - CLTX (63):
c) an outer layer of the tubular member formed of a polymeric material which is more flexible than the inner layer polymeric material and which has a **melting point** at least 20.degree. C. less than the **melting**

point of the inner
layer.

Claims Text - CLTX (69):
51. An intralumenal catheter part comprising an elongated multilayered
tubular member having an inner lubricious layer and an adjacent outermost
polymeric layer formed of a polyolefin polymerized with up to about 35% by
weight of a polymer having reactive monomer groups, the adjacent polymeric
layer having a **melting point** of at least 20.degree. C. less than the inner
layer.

Claims Text - CLTX (70):
52. The intralumenal catheter part of claim 51 wherein the polymeric layer
adjacent the inner lubricious layer has a **melting point** of at least about
30.degree. C. less than the inner layer.

Claims Text - CLTX (74):
a) an elongated shaft having proximal and distal ends, a port in the distal
end and a **guidewire** lumen extending therein to and in fluid communication with
the port in the distal end;

Claims Text - CLTX (75):
b) a multilayered tubular member having an inner layer formed of a
lubricious polymeric material which defines in part the **guidewire** lumen and an
outer layer formed of a polymeric material having a lower **melting point than**
the melting point of the polymeric material of the inner layer; and

Claims Text - CLTX (76):
c) a non-traumatic distal tip on the distal end of the catheter formed by a

tubular member formed of flexible polymeric material which is secured to the
outer layer of the multilayered tubular member or the distal end thereof, the
distal tip having an outer layer and an inner layer, the inner layer being
formed of low **melting point** polymeric material to facilitate **fusion** bonding to
the outer layer of the multilayered tubular member.

Claims Text - CLTX (77):
56. The catheter of claim 1 having a non-traumatic distal tip secured to
the outer layer of the multilayered tubular member by **fusion** bonding.

Claims Text - CLTX (78):
57. The catheter of claim 55 wherein the outer layer of the multilayered
tubular member has a **melting point** of at least about 20.degree. C. less than
the inner polymeric layer of the multilayered tubular member.

Claims Text - CLTX (79):
58. The catheter of claim 55 wherein the outer layer of the multilayered
tubular member has a **melting point** of at least about 30.degree. C. less than
the inner polymeric layer of the multilayered tubular member.